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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,441	12/18/2001	Martin J. Jacobs	CP216	2296

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,441	JACOBS ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006 and 23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *99-110,112-129 and 131-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *99-110,112-129 and 131-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2006 has been entered.

Claims 111 and 130 have been canceled. Claims 99 and 126 have been amended. New claims 135 and 136 have been added. Claims 99-110, 112-129 and 131-136 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed January 20, 2006 is sufficient to overcome the rejection of the claims based upon 35 USC § 103 over the references discussed in the previous Office action. The examiner agrees that the relative increase in solubility amounts to unexpected results. However, these results are not commensurate with the scope of the claims. The claims have been amended to require a modafinil solubility of at least about 30 mg/mL. It is not clear that all the recited cyclodextrin have the capacity to provide the relative increase the solubility in order to solubilize the modafinil to the required concentration. See discussion below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 99-110, 112-129 and 131-136 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydroxypropyl–β–cyclodextrins (HPBCD) and β–cyclodextrin sulfobutyl ether (SBE–β–CD), does not reasonably provide enablement for the full range of cyclodextrins recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;
(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

As noted in Pitha, of record, HPBCD is a highly soluble CD. At a composition of 50%, the concentration of HPBCD is about 355 mM. At 30 mg/mL, the concentration of modafinil is about 110 mM. Szejtli (Chem. Rev., 1998) teaches that the underivatized CDs (α–, β– and γ–) are much less soluble, with maximum solubilities of 149 mM, 16 mM and 180 mM, respectively. See Table 1. Although α–CD and γ–CD are soluble enough to form at least 1:1 complexes with

some excess, it is not clear what the minimum excess (if any) is required to obtain this recited concentration of modafinil or if it will interact with these differently sized CD cavities in such a way to support this concentration.

SBE–β–CD is known to be very soluble. The CyDex bulletin teaches that the maximum concentration of SBE–β–CD is 370 mM. (Due to difficulties in getting the entire document to print properly, only one page of the bulletin is being provided. However, the entire document may be accessed online at http://www.cydexinc.com/maxdocs/Cyclodextrin-derivatives.pdf.) Because of the known facility for solubilizing compounds, it would appear likely that one would see similar results with this derivatized CD.

The claims are drawn to the use of any cyclodextrin, but many seem unlikely to have the solubilizing capability to provide modafinil solution having the recited concentration. The instant specification provides working examples for HPBCD only. Therefore, although one of ordinary skill would have a high degree of skill, it would require undue experimentation for the artisan to prepare the required composition using cyclodextrins other than HPBCD or SBE–β–CD.

Claims 99-110, 112-129 and 131-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the limitation "at least about 30 mg/mL." The phrase, "at least about 30 mg/mL" is indefinite. Ranges of more or less than "about" are inherently unclear. For example, would that language cover 25 mg/mL? That is not clear. Since it is less than 30 mg/mL, it would seem not, but since "about 30 mg/mL" would cover some range less than 30 mg/mL, it is

not clear what the scope of the claim is. See *Ex parte Lee*, 31 USPQ 2nd 1105, 1107; *Amgen vs. Chuggai*, 13 USPQ 2nd 1737, 1787; 18 USPQ 2d 1016, 1030. Deletion of the "about" is suggested.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
April 7, 2006